

# BNAC

BRITISH-NORTH AMERICAN COMMITTEE

## A Guide to the Benefits, Responsibilities and Opportunities of Embryonic Stem Cell Research

**British-North American Committee**

Sponsored by

The Atlantic Council of the United States

British-North American Research Association (UK)

C.D. Howe Institute (Canada)

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## The British-North American Committee

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The British-North American Committee is a group of leaders from business, labor, and academia in the United Kingdom, the United States, and Canada committed to harmonious, constructive relations among the three countries and their citizens. It meets regularly to discuss common concerns with invited experts and senior policymakers in an off-the-record setting, and its regular research and publishing program seeks to discover and disseminate potential solutions. While nonpartisan and supportive of closer economic and political relations on a broad international basis, the BNAC believes that close personal ties and cooperation among leaders from various spheres in the three countries will in the future, as in the past, play a special role in promoting global security and prosperity.

Implicit in the Committee's existence is recognition that the three countries share ties that go beyond economic and security questions, extending to issues of culture and habits of mind. Although the Committee has never sought to be a policy institute, its regular commissioning and publishing of research — generally accompanied by signed statements of members' views — testifies to its members' desire to disseminate useful analysis of issues of common concern.

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The views expressed in this publication are those of the authors and those BNAC members who have endorsed it (*see page vii*). They do not necessarily reflect the views of the BNAC membership as a whole, nor of the Atlantic Council of the United States, the British-North American Research Association and its Council and Members, or the C.D. Howe Institute's Board of Directors.

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# Contents

A BNAC Statement on Embryonic Stem Cell Research .....	v
Members of the Committee Signing the Statement.....	vii
Executive Summary.....	ix
Stem Cell Technology: Summary of the Scientific Background.....	1
The Ethics of Embryonic Stem Cell Research.....	9
A Review of Legislative and Regulatory Activity in the United States, ..... United Kingdom, Canada, and Selected Other Countries	19
Some Economic Consequences of Embryonic Stem Cell Policy.....	25
Conclusions.....	29
Members of the British-North American Committee.....	33
Publications of the British-North American Committee.....	39
About the Sponsoring Organizations .....	41

# Tables and Figures

Table 1: Potential Use of Stem Cells to Treat Disease/Damage.....	2
Table 2: Types of Stem Cells.....	2
Figure 1: Fertilization of a Human Ovum, Early Stage Development, and Extraction of ESCs.....	3
Table 3: Embryonic Stem Cells from Embryos Created by IVF — Key Features .....	4
Figure 2: Embryonic Stem Cells from Somatic Cell Nuclear Replacement (SCNR) — Key Steps.....	5
Table 4: Stem Cells Derived from Embryos Created by SCNT — Key Features.....	5
Public Opinion in the United States .....	13
Public Opinion in the United Kingdom.....	14
Public Opinion in Canada .....	15
Legislative and Regulatory Activity in Selected Nations and Multinational Organizations.....	20
Legislative and Regulatory Activity in the United States, by State .....	21

## **A BNAC Statement on Embryonic Stem Cell Research**

At recent British-North American Committee meetings, we have discussed public policy aspects of embryonic stem cell research. A “stem cell” is an unspecialized cell at an early stage of development that has the potential to divide and become specialized into a large number of cells that make up the tissues and organs of the body. Under appropriate conditions, stem cells can self-renew, i.e. reproduce themselves for long periods. In this way “cell lines” (large collections of identical, characterized cells) can be produced for experiments and potentially for clinical use.

Embryonic stem cells are one kind of stem cell, distinguished from both fetal and adult stem cells. The general consensus of the scientific community is that a greater understanding of embryonic stem cells has the best potential for advancing medical knowledge.

We focused on this subject because it has major potential for improving human welfare and yet raises many contentious issues. It is our opinion that an informed public debate on the topic must be stimulated in our three countries. In this way, the inherent technical and ethical problems can be properly considered. This report is one contribution to that debate.

We believe that global embryonic stem cell research will contribute to the ultimate benefit of human health. Furthermore, the economic benefits will flow to those who participate in the advancement of knowledge in this area.

While recognizing and acknowledging the complex ethical issues involved, we recommend that:

1. The national scientific research policies of the United States, United Kingdom, and Canada should reflect the intent to lead the world in the evolving knowledge base, likely medical advances and economic benefits of embryonic stem cell research.
2. The scientific objective should be to maximize the potential therapeutic benefits of embryonic stem cell research for all humanity.
3. The barriers and objections to this scientific objective need to be addressed in each country by way of open public debate, guided by objective information, in which the concerns of all stakeholders can and should be actively considered and balanced.
4. To assist in this public debate, the economic and scientific risk-reward equation needs to be quantified by relevant and objective experts in our countries.
5. Laws and regulations need to be introduced to govern the conduct of research, the preservation of privacy and property, and the use of public funds in a manner that will foster sound public policy and strong leadership in our countries on this important issue.

The endorsement of this study by the undersigned does not necessarily mean each BNAC member agrees with everything in it. We do, however, commend this paper and our recommendations for wider discussion among policymakers, commentators, the medical establishment and the general public (including patient groups). We hope this study will promote a balanced and inclusive approach to the development of this promising technology.



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Pace Micro Technology Plc  
Kent, England

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Chairman-designate of Royal Holloway,  
University of London and Former High  
Commissioner to Canada  
Somerset, England

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Haruspex Consulting  
Oxford, England

PHILIP DECK

Managing Partner  
HSD Partners, Inc.  
Toronto, Ontario

DR. RICHARD de NEUFVILLE

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Technology and Policy Program  
Mass. Institute of Technology  
Cambridge, Massachusetts

MAUREEN FARROW

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Economap Inc.  
Toronto, Ontario

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Foresight VCT plc  
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Toronto, Ontario

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Montréal, Québec

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Toronto, Ontario

DAVID LEVY, M.D.

Former Chairman and CEO  
PersonalPath Systems, Inc  
Upper Saddle River, NJ

PIERRE LORTIE

President & CEO  
Bombardier Transportation  
Saint-Bruno, Québec

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Atlantic Council of the United States  
Washington DC

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London

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C.D. Howe Institute  
Toronto, Ontario

DEREK OLAND  
Chairman & CEO  
Moosehead Breweries Limited  
Saint John, New Brunswick

JACQUELINE OLAND, B.V.M.S.,  
M.R.C.V.S.  
Saint John, New Brunswick

RONALD OSBORNE  
Chairman, BNAC Executive Committee  
Toronto, Ontario

SIR BRIAN PITMAN  
Senior Advisor  
Morgan Stanley & Co International  
London

NEIL RECORD  
Chairman  
Record Currency Management Ltd  
Windsor, England

ARTHUR R. A. SCACE  
Partner  
McCarthy Tétrault  
Barristers & Solicitors  
Toronto, Ontario

THOMAS H. B. SYMONS, C.C., O.Ont.,  
FRSC.  
Founding President, Trent University,  
Chairman of the National Statistics Council of  
Canada

BARBARA THOMAS JUDGE  
Deputy Chairman  
Financial Reporting Council  
London

WILLIAM I.M. TURNER, JR.  
Chairman and CEO  
Exsultate Inc.  
Montreal, Quebec

SIMON WEBLEY  
Research Director  
Institute of Business Ethics  
London

VISCOUNT WEIR  
Chairman  
CP Ships  
London

KERN WILDENTHAL, M.D.  
Austin, Texas

DAVID A. WILSON, Ph.D.  
President & CEO  
Graduate Management Admission Council  
McLean, Virginia

SIR ANTHONY YOUNG  
Trade Union Liaison Officer  
The Ethical Trading Initiative  
Southall, England

## Executive Summary

Embryonic stem cells (ESCs) offer potentially revolutionary insights into health and disease, and hope for cures to illnesses that were not imaginable just a few years ago. Unfortunately, the entire subject has been fraught with confusion and emotion, the result of which has driven our countries to create laws and regulations that could ultimately prove detrimental to the human condition of our citizens, to our leading positions in biomedical research, and ultimately, to our economies.

The purpose of this guide is to create the framework for an informed discussion regarding ESC research. Four specific areas are reviewed — the scientific background, ethical concerns, legislative activity in our three countries and elsewhere, and the potential impact on our economies and well being of our citizens.

Embryonic stem cells are one kind of stem cell, distinguished from both fetal and adult stem cells. The general consensus of the scientific community is that a greater understanding of embryonic stem cells has the best potential for advancing medical knowledge.

There are three sources of ESCs — excess embryos as a by-product of *in vitro* fertilization (IVF), deliberate fertilization of human ova in culture, and somatic cell nuclear transplantation (SCNT), sometimes called therapeutic cloning. The first two sources are from human sperm and ova combining outside of the human body in laboratories, the result of which is an embryo with a new genetic complement of cells, just like normal fertilization (one half the genetic material each from the mother and father). The third source derives all of its genetic material from a somatic cell (adult non-sperm cell), and is transplanted in the laboratory into human ova. The resulting embryo thus is an almost exact genetic replica of the somatic cell donor.

The ethical considerations of ESC research are considerable, and often confusing. The confusion arises due to a general lack of awareness of the sources of ESCs, and their distinguishing characteristics. The stakeholders are the scientific community, religious and philosophical leaders, and the general public. Policy makers translate the desires of their constituents into legislation, which is examined separately in this guide.

The scientific communities of our three countries, while not without concerns, are generally highly supportive of ESC research, and believe they possess the appropriate ethical framework to conduct research. Religious and philosophical leaders are most concerned about the destruction of human embryos, which many consider to be a human life at these early stages.

Many are also concerned that research and development of the third source of ESCs — SCNT or therapeutic cloning — will hasten the arrival of true human cloning, where these embryos are re-implanted into a uterus to produce a human being that is a genetic replica of the somatic cell donor. The public, while not exclusive to the other groups, is most excited about the opportunities to cure diseases that have so far benefited relatively little from modern research, and possibly alleviate the meager supply of organs for transplantation using genetically identical newly grown organs. Concerns, however, reside in issues of privacy, property, informed consent, and cost.

Policy makers are left with the task of enacting policy and legislation that help the most and hurt the fewest. This is necessarily done in an environment of rapidly changing knowledge, and in consideration of many stakeholders, each with varying degrees of influence.

A review of legislative activities showed that the United Kingdom has established the clearest and most consistent policies and legislation of our three countries. Federal law and regulations in the United States determine the absence or presence of federal funding of ESC research, while state laws are generally enacted for the purpose of supporting the private sector. In the United States there is a lack of internally consistent laws and regulations between the states and at the federal level that address ESC research. Canada has recently passed legislation banning ESC research from all stem cell sources other than from excess embryos available from IVF. ESC research is fully supported and progressing rapidly in countries such as China, South Korea, and Singapore.

There is no question that economic consequences will be associated with the legislative and policy decisions of our three countries regarding ESC research. Two distinct constructs were examined; i) the 'economics of discovery', with the value creation dimensions of simple financial return, and the flow of human knowledge and human capital, and ii) the 'economics of distribution', where if distribution were precluded, both research and its fruits are likely to go underground with the resulting financial benefits siphoned off by others. The economics of discovery and distribution are likely to determine which countries will win and which will lose in this new and exciting field of medical research.

Of note is the authorship of this manual. The British-North American Committee consists of a group of accomplished individuals from all walks of life. There is no specific and inherent expertise in this area of science or ethics. Our task as concerned generalists was to produce a piece of work that we could all understand and use.

June 2004

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# Stem Cell Technology:

## Summary of the Scientific Background

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All living organisms are made up of cells. Most cells in a developed organism, such as a human body, are “specialized” in the sense that they make up distinct parts of the body such as bone, heart, muscle, blood, etc.

There is a period after fertilization during which living organisms have relatively few cells, most of which are “unspecialized” — because the distinct body parts have not yet been formed. Unspecialized cells are able to divide and develop over time, through intermediate cells that can produce families of specialized cells, and then finally become the specialized cells themselves, which form the distinct body parts.

A “stem cell” is an unspecialized cell at an early stage of development that has the potential to divide and differentiate (become specialized) into a large number of cells that make up the tissues and organs of the body. Under appropriate conditions, stem cells can self-renew, i.e. reproduce themselves for long periods. In this way “cell lines” (large collections of identical, characterized cells) can be produced for experiments and potentially for clinical use.

With some notable exceptions, specialized cells are not capable of re-growing nor replacing diseased or damaged parts of the body. However, if the process by which stem cells grow and divide into specialized cells can be understood and replicated, there is the possibility of replacing specialized cells in diseased or damaged tissue and, even, of re-growing parts of the human body with genetically identical material to that of the recipient, thereby avoiding the problem of tissue rejection.

This is why stem cell research — i.e. finding out how stem cells work — is such an important and exciting field for medical research. The potential of stem cells is that they could be stabilized and grown in the laboratory, and then influenced to differentiate into mature cells or form tissues, such as skin, heart muscle, or insulin-producing pancreatic cells, that could then be used to replace damaged parts of the body.

The scope for stem cell therapy is enormous. Organs damaged by trauma or disease do not always need to be replaced completely (transplantation), and repair would be possible if a sustainable source of cells were available. The aim would be to colonize host organs or tissue with sufficient normal cells to restore their physiology or accelerate the repair of damage. The treatment of extensive burns and complex fractures could also benefit from this approach. Some of the potential tissues that could be repaired by these techniques are listed in *Table 1*.

The obvious source for stem cells for research is the embryo in the few days following conception, because at that stage most of the cells in the embryo are unspecialized. Some adult tissues contain stem cells that have a more restricted differentiation potential (e.g. bone marrow). However, recent reports have shown that they too can be induced to form other tissues. Using a technique called “cell nuclear transfer” adult cells can be reprogrammed to become stem cells, in effect ‘turning the clock back’ so they behave like unspecialized stem cells again.

There are three main sources of stem cells (see Table 2). They differ in the ease with which they can be expanded in number in the laboratory and in the range and types of mature tissue cells they can be induced to make.

Table 1 Potential Use of Stem Cells to Treat Disease/Damage	
Cell Type	Target Disease
Neural cells	Stroke, Parkinson’s and Alzheimer’s disease, spinal cord injury, multiple sclerosis
Heart muscle cells	Heart attacks, congestive heart failure
Insulin-producing cells	Diabetes
Cartilage cells	Osteoarthritis
Blood cells	Cancer, immunodeficiencies, inherited blood diseases, leukemia*
Liver cells	Hepatitis, cirrhosis
Skin cells	Burns, wound healing
Bone cells	Osteoporosis
Retinal (eye) cells	Macular degeneration
Skeletal muscle cells	Muscular dystrophy

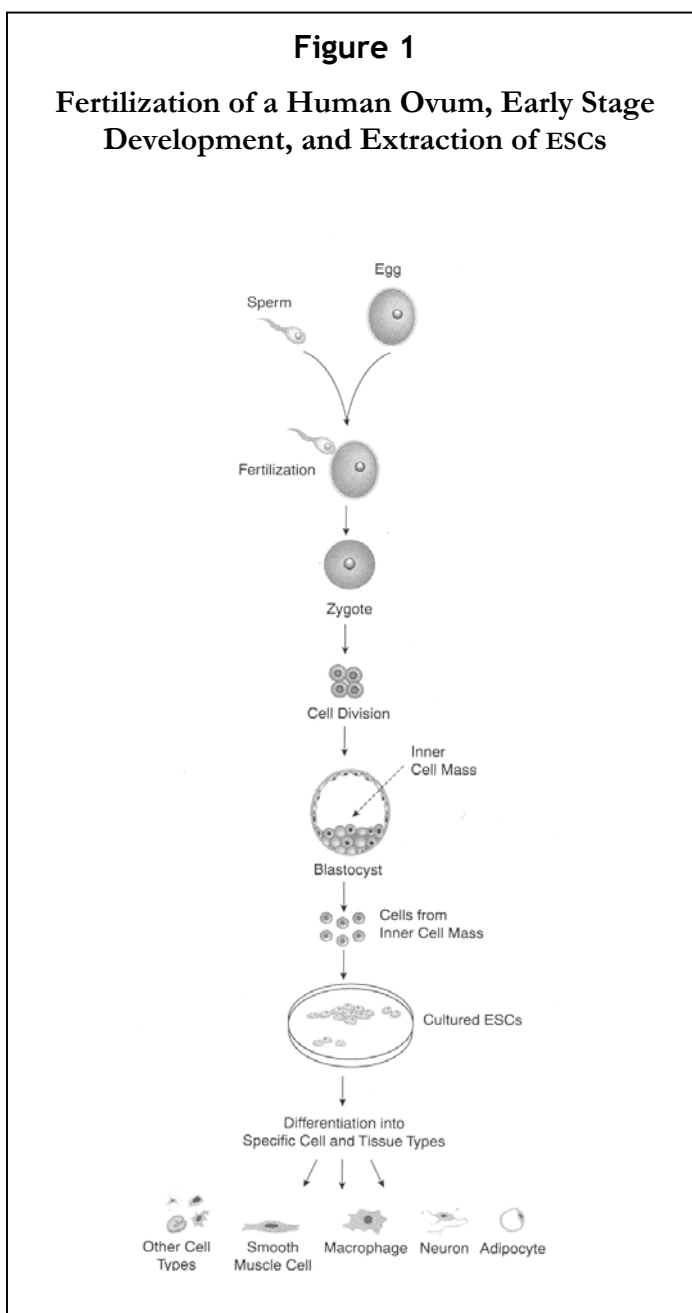
Table 2 Types of Stem Cells
<p><b>Embryonic Stem Cells (ESCs)</b></p> <ul style="list-style-type: none"> <li>• From <b>early embryos (blastocysts) created by <i>in vitro</i> (test tube) fertilization (IVF)</b> — either those which are needed for infertility treatment (sometimes called ‘spare embryos’) or created specifically for research (allowed in very few countries);</li> <li>• From early embryos created by inserting the nucleus from an adult specialized (somatic) cell into an egg with its nucleus removed — <b>somatic cell nuclear transfer</b> (sometimes called SCNT, or “<b>therapeutic cloning</b>”).</li> </ul>
<p><b>Fetal Stem Cells</b></p> <ul style="list-style-type: none"> <li>• From the germ cells or organs of an aborted fetus;</li> <li>• From the blood cells of the umbilical cord or placenta of a newborn.</li> </ul>
<p><b>Adult Stem Cells</b></p> <ul style="list-style-type: none"> <li>• From some adult tissues (such as bone marrow);</li> <li>• From mature adult cells reprogrammed to behave like stem cells.</li> </ul>

## Embryonic Stem Cells (ESC)

It is generally agreed within the scientific community that stem cells derived from early human embryos hold the greatest potential for differentiation into different types of tissue cells, and for this reason they are called “pluripotent.” These cells, taken from the inner cell mass of an embryo at the “blastocyst” stage of development (about 5 to 6 days after fertilization) before specialization has begun, appear to have the ability to differentiate into nearly any cell type. After the blastocyst stage, the opportunity to extract embryonic stem cells is gradually lost as the stem cells start to become specialized and no longer have the potential to become all types of tissue.

The ability to retrieve embryonic stem cells from blastocysts at this early developmental phase only became realized with the advent of IVF in the 1980s, when ova and sperm were united outside the female body, a technique commonly known as “test tube babies” and used for infertile couples. In this situation, ova and sperm were united in a petri dish, and blastocysts not used for re-implantation into the mother were readily available for research use. By the late 1990s, the subsequent extraction and successful culture of embryonic stem cells from these blastocysts was first executed. Since then, researchers have been able to maintain stem cell lines for extended periods, also demonstrating that the cells can be frozen for storage and then thawed when required for use.

Embryonic stem cells from fertilized embryos have two general sources — one is the excess fertilized embryos left over during the process of in-vitro fertilization (IVF) currently used for non-fertile couples seeking to have children, and the other is the deliberate fertilization of ova with sperm, created the same way as IVF, but extracted and used explicitly for research of this kind (allowed in a few countries). *Figure 1* is illustrative, and *Table 3* describes some key features.



<p><b>Table 3</b></p> <p><b>Embryonic Stem Cells from Embryos Created by IVF — Key Features</b></p>
<ul style="list-style-type: none"> <li>• Embryos are fertilized <i>in vitro</i> (in a test tube).</li> <li>• Embryos from IVF can be donated, with appropriate consents, for research when no longer needed for infertility treatment.</li> <li>• Stem cells are removed after 5-6 days of embryonic cell divisions.</li> <li>• Resulting stem cell lines are capable of differentiating into a wide range of tissues.</li> <li>• Tissue resulting from stem cell culture is not normally genetically identical with the person being treated (i.e. rejection has to be counter-acted by the use of agents that suppress the immune system).</li> </ul>

Stem cells extracted from the blastocyst stage of a human embryo created by the technique of “somatic cell nuclear transfer,” also known as “SCNT” or “therapeutic cloning,” are thought to have the same potential to differentiate into as wide a variety of cell types as stem cells derived from embryos created by fertilization of an egg with sperm. Somatic cell nuclear replacement (SCNT) involves inserting a cell nucleus that contains the DNA from a specialized cell of an adult (somatic cell) into an unfertilized egg (“oocyte”) which has had its own nucleus removed (“enucleated”), and stimulating this cell line *in vitro* (test tube) to the blastocyst stage of development. A key difference between these embryonic stem cells and those derived from IVF is that the genetic material in this technique is envisaged to be identical to the genetic material of the nucleus donor, whereas in IVF the genetic material of the blastocyst is that which results from the union of the sperm and the egg, or a 50-50 split. Somatic cell nuclear transfer offers the potential for tissue and organ replacement without the worry of tissue rejection of the host — although there are complications. For example, animals born from embryos generated by cell nuclear replacement are not exactly identical to the animal whose adult cell nucleus was used in the process. They inherit mitochondrial DNA (contained in the outer layer of the egg) from the enucleated egg used in the replacement process. The implications of this for the compatibility of tissue derived from embryos created by cell nuclear replacement require further research.

The process by which these activated ova (with genetic material from a somatic cell of a donor) are reimplanted into a female for the purpose of reproduction is called “cloning.” This was first achieved successfully in the 1990s with the creation of Dolly the sheep, the first cloned mammal, and has since been reproduced in other mammalian species. However, when these blastocysts are not reimplanted in females, and are grown in test tubes specifically to extract embryonic stem cells for the purpose of research, the process is called “therapeutic cloning.” “Human cloning” has universally been declared to be unsafe and ineffective by world medical and scientific bodies and is illegal in most countries. Therapeutic cloning, fully accepted as a legitimate research tool for the advancement of medical science by world scientific organizations, has nevertheless created enormous controversy and confusion. *Figure 2* describes this process and *Table 4* describes some key features.

**Figure 2**  
**Embryonic Stem Cells from Somatic Cell Nuclear Replacement (SCNR) — Key Steps**

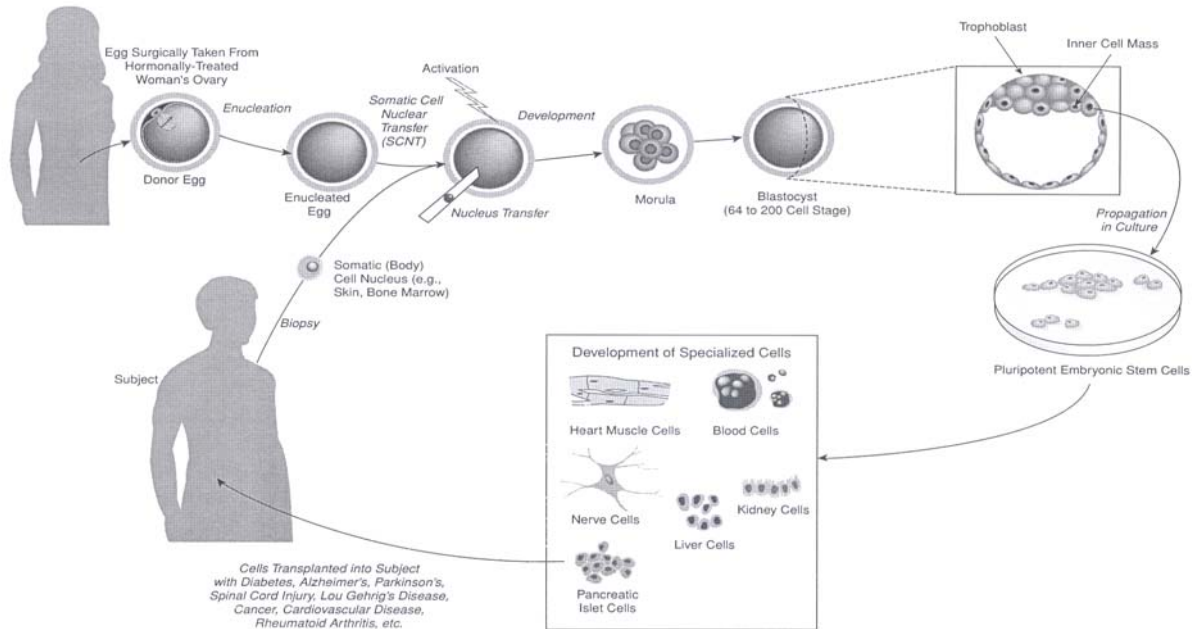


FIGURE 2 Nuclear Transplantation to Produce Stem Cells

Scientific & Medical Aspects of Human Reproductive Cloning  
 Copyright © National Academy of Sciences

**Table 4**

**Stem Cells Derived from Embryos Created by SCNT — Key Features**

- Embryos are created by replacement of the nucleus of an unfertilized egg with the somatic cell nucleus of a donor.
- Stem cells are taken after 5 to 6 days of embryonic cell divisions.
- Resulting stem cell lines could be capable of differentiating into a wide range of tissues.
- Tissue resulting from stem cells could be genetically identical with the person being treated (i.e. no rejection).

## Other Types of Stem Cells

### Fetal Stem Cells

Stem cells very similar to embryonic stem cells have been grown in culture from primitive fetal reproductive tissue collected in the first 6 weeks of fetal development. These stem cells are known as “embryonic germ cells” and have the potential to develop into a wide range of tissues. Such cells have been derived from human fetal tissue obtained after miscarriage or abortion, and from the umbilical cord and placenta.

### Umbilical Cord Stem Cells

Cord blood is rich in stem cells but these appear to have limited ability to differentiate — they may only produce blood cells or bone marrow cells. In the future, it may be possible to change the programming of these stem cells so they mature into a wider range of tissues.

### Adult Stem Cells

Stem cells have been isolated and cultured from adult tissues such as bone marrow and arterial and venous blood for some years. These have been used in transplantation (to treat leukemia, for example), and in some single gene disorders. Stem cell lines derived from adult tissue have until recently been thought to have very limited potential for specialization into other types of cell. However, more recent research has shown that adult stem cells can differentiate into unrelated cell types, such as nerve and blood cells in some circumstances.

A further line of research is to try to program an adult cell to make it revert to its unspecialized state so that it can then be influenced to develop into a different type of tissue. This will require not only an understanding of how unspecialized cells form specialized cells but also how to reverse the process of specialization. Advances were reported by the Scripps Research Institute late in 2003, with the announcement of the identification of a synthetic molecule that can induce a cell to undergo de-differentiation — to move backwards developmentally from its current state to form its own precursor, a less specialized cell.

Another even more recent and potentially exciting line of research is to try to reprogram the small population of stem cells known to exist in the vicinity of damaged and diseased tissues of mammals to effect local repair *in vivo* (i.e. in the body itself). This would directly circumvent problems of immune rejection, reduce the use of embryos and reduce the costs of isolating and banking cell lines. There is some exciting research going on in this area in mice — but it is at a very early stage.

## Summary

The science of stem cells is still at an early stage of development. If stem cells are to realize their potential in the treatment of disease and damage in mammals, two stages of work have to be completed:

- First, a thorough understanding of how stem cells work. This includes the need to elucidate the origin of the various types of differentiated cells and how the process of differentiation is started, stabilized and reversed, as well as the need to develop the techniques necessary to build and maintain required cell lines.
- Second, the application of this knowledge from the first stage to the treatment of damage and disease i.e. to use stem cells for therapeutic purposes.

These two stages are interactive, and it is possible (and probably necessary) to experiment with the second stage in order to gain better understanding of the first. The ideal long-term target for research might be defined as finding a way to encourage diseased and damaged tissue to heal itself *in vivo* — to “re-grow” — without problems of rejection. New discoveries are occurring every month in this field, and the path of discovery is evolving quickly in the first stage of knowledge. It is not unreasonable to hope that the fruits of this basic science will lead to the development of therapies — the second stage — in a time frame measured in years rather than decades.

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The authors would like to acknowledge the following publications that provided invaluable briefing and source material for this chapter:

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# The Ethics of Embryonic Stem Cell Research

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ESCs are currently derived from three sources — excess embryos from *in vitro* fertilization (IVF), deliberately fertilized embryos for research, and somatic cell nuclear transfer (SCNT, or therapeutic cloning). The first two sources are a result of the laboratory union of egg and sperm, and the latter is the result of the laboratory implantation of the nucleus of an adult somatic cell into a human egg.

The ethical and moral dilemmas around ESC research are derived from two main issues — the fact that the first two sources are indeed from *bona fide* human embryos, and that therapeutic cloning — while *per se* not typical human embryos — have the potential for creating human life if implanted into women, exactly like that achieved with the successful cloning of other mammalian species. The key constituencies are the international scientific community, the general public, religious/philosophical leaders, and legislators.

**1) The international scientific community** regards ESCs as a unique and rich potential source of research and therapy that may improve the quality of life. They argue the following points:

- In order to maximize the value of ESCs, extensive basic scientific research is needed.
- Human ESC research is more likely to result in more targeted and effective human therapies.
- The explosion in knowledge of the human genome is likely to offer synergies with the output of ESC research.
- Basic scientists have a sufficient moral and ethical framework and consensus to conduct responsible work.

The informed scientific community has some concerns:

- Misrepresentation of appropriate research activities by other vested interests.
- Restrictive legislation forcing research ‘underground’ or elsewhere.
- Retaliatory tactics instigated by those driven by ideology, misinformation and fear towards the scientific community which could impact other areas of research funding and support.

**2) Religious and philosophical leaders** are more likely to view the issues as absolute, and some will readily bless or condemn practices deemed acceptable and unacceptable. The most extreme and often the most vocal argue the following points:

- The blastocyst is “human life” and any destruction thereof is tantamount to the destruction of life.
- Therapeutic cloning, while technically not human life, is a precursor to human cloning, which is immoral.

However, many religious and philosophical leaders try to hold a balanced middle ground — recognizing the tremendous potential for the enhancement of life versus the moral and ethical dilemmas of the artificial creation and destruction of life. For them, the challenges are where to draw a line, and how to provide guidelines based on ethical reasoning. For example, in some countries where one or two sources of ESCs have been sanctioned, a working time limit to distinguish between a collection of cells and a fertilized embryo has been set at 14 days post-fertilization, in an effort to achieve this balance.

**3) The general public** admittedly is not a group mutually exclusive to the others. While influenced by religious and ethical leaders, legislators, and the scientific community, the public reacts very directly to the tangible benefits and liabilities, namely the diseases that could be cured and what it means to health care affordability. Other important issues are: property of embryos, privacy, and scientific disclosure. The public cares about:

- The wide variety of medical conditions potentially curable.
- The shortage of organs for transplantation and the problem of organ rejection.
- The protection of privacy issues related to the donation of embryos, and the need to provide full scientific disclosure, with respect to usage of embryos and derivative ESCs.
- The direct impact of cost.

**4) Policy makers** are left with the task of making informed decisions that provide the greatest benefit to the largest number of people, and the least harm to the smallest number. These decisions are necessarily made in an environment of quickly evolving knowledge, and are complicated by the lobbying of all the above constituencies. They must address the following:

- Government funding for ESC research.
- Patents and other intellectual property rights that result from this research.
- Regulation of consent, privacy, disclosure, dignity and health of individuals who donate research material, and ownership and payment for biologic materials.
- Appropriate application and commercialization of discoveries.
- Use and abuse of biologic material — manipulating embryonic genetic material, transfer to humans for implantation (human cloning), trans-species use, etc.

The potential impact on the electorate as a consequence of the actions of the body politic is enormous, and is examined in the next chapter.

## **Public Opinion in the United States, the United Kingdom and Canada**

Accurate data reflecting the public's attitude to embryonic stem cell research are central to the ongoing debate about this complex subject. Politicians, the scientific community, patient groups and the media need to know how the public views issues such as federal vs. state funding, therapeutic vs. reproductive cloning, and how opinions on these issues change over time.

The following are descriptions of surveys recently conducted in Canada, the United Kingdom and the United States. While not exhaustive, they give a good indication of the public's current feelings towards ESC research.

### **1. Public Opinion in the United States**

Since 2000, several public opinion polls have been conducted in the United States on the issue of therapeutic cloning. Results consistently show that the U.S. public generally opposes reproductive cloning, but is in favor of therapeutic cloning research (SCNT).

For example, in March 2003 Opinion Research Corporation International conducted a public opinion poll on behalf of the Coalition for the Advancement of Medical Research (CAMR)<sup>1</sup>. CAMR is comprised of U.S. patient groups, universities, and scientific societies. It has spearheaded the political campaign against a ban on therapeutic cloning. The poll asked the opinion of 1,012 adults. The headline results were:

- 67% favor the continuation of therapeutic cloning research.
- 55% want Congress to ban reproductive cloning but allow therapeutic cloning.
- 30% want a ban on therapeutic and reproductive cloning.
- 12% want no ban on either form of cloning.
- 3% were undecided.

These 2003 results essentially confirm those from a similar poll conducted in 2002, which some observers have found surprising. They had believed that the flurry of hoaxes regarding reproductive cloning would confound the U.S. population so that they would confuse therapeutic cloning with reproductive cloning, and thus oppose both.

### **2. British Public Opinion**

In 2003 MORI, a leading UK-based public opinion research organization, conducted a public opinion poll commissioned jointly by a coalition of several public sector and charitable organizations involved in medical research<sup>2</sup>. MORI interviewed a representative quota sample of 2,001 respondents aged 15 or older throughout Great Britain across 201 sampling points (twice the size of the 2003 American poll referred to above). The results of the poll showed:

- Around 70% of the British public support the use of human embryos for medical research to find treatments for serious diseases and for fertility research

- Over 50% feel that the use of human embryos for medical research is only acceptable to find treatments for serious diseases and for fertility research, but not for most other types of research
- One in six feels the use of human embryos is always acceptable for all types of medical research.

The first of these findings is in line with U.S. public opinion. The second two areas were not reported by the US survey.

### 3. Canadian Public Opinion

In October 2003 a national survey was conducted by the research firm Pollara, questioning 1,375 adult Canadians<sup>3</sup>. The poll found that 57% of those surveyed approve of allowing stem cell research on human embryos that are either left over from fertility treatments or created for such research. 64% agreed the federal Government should provide funding for this scientific research.

However, the poll also suggests many people are unfamiliar with the issue. One in five Canadians, or 20%, did not have an opinion or refused to answer.

The poll also found that men (64%) are more favorably disposed toward embryonic stem cell research than women (54%). Embryonic stem cell research enjoys majority support across all age groups and all regions in Canada, the survey found, although support was strongest in Quebec at 63%. Quebec also topped the chart in support for government funding of such research at 68%.

#### Opinion of key constituencies

The following tables review the current positions of several scientific, religious, and lay groups on ESC research. The organizations cited in the following tables were chosen purely for illustrative purposes, rather than to give a representative sample of opinion in each constituency.

Key			
✓	In Favor	⊗	Opposed
▼	Controlled	□	No Opinion

**United States**

	<i>In Vitro</i> Fertilization: excess embryos	<i>In Vitro</i> Fertilization: created for research only	Somatic Cell Nuclear Transfer (SCNT) - "Therapeutic Cloning"
<b>SCIENCE</b>			
National Academies of Science (NAS) <small>4</small>	▼	▼	▼
National Institutes of Health <small>5</small>	▼	▼	▼
<b>RELIGION &amp; PHILOSOPHY</b>			
Christian Coalition <small>6</small>	⊘	⊘	⊘
National Council of Bishops <small>7</small>	⊘	⊘	⊘
Rabbinical Council of America <small>8</small>	✓	✓	✓
Hastings Center <small>9</small>	▼	▼	▼
President's Council on Bioethics (PCBE) <small>10</small>	⊘	⊘	⊘
<b>PUBLIC</b>			
American Assn. for the Advancement of Science <small>11</small>	▼	▼	▼
American Association of Retired Persons (AARP) <small>12</small>	□	□	□
Biotechnology Industry Organizations (BIO) <small>13</small>	▼	▼	▼
Coalition for the Advancement of Medical Research (CAMR) <small>14</small>	▼	▼	▼
Democratic National Committee <small>15</small>	□	□	□
Republican National Committee <small>16</small>	□	□	□

**United Kingdom**

	<i>In Vitro</i> Fertilization: excess embryos	<i>In Vitro</i> Fertilization: created for research only	Somatic Cell Nuclear Transfer (SCNT) - "Therapeutic Cloning"
<b>SCIENCE</b>			
Biotechnology and Biological Sciences Research Council <small>17</small>	▼	▼	▼
Department of Health <small>18</small>	▼	▼	▼
Medical Research Council <small>19</small>	▼	▼	▼
<b>RELIGION &amp; PHILOSOPHY</b>			
The Guild of Catholic Doctors <small>20</small>	⊘	⊘	⊘
Christian Medical Fellowship <small>21</small>	⊘	▼	⊘
Nuffield Council on Bioethics <small>22</small>	▼	▼	▼
Pro-Life Alliance <small>23</small>	⊘	⊘	⊘
Royal Society <small>24</small>	▼	▼	▼
<b>PUBLIC</b>			
Bioindustry Association <small>25</small>	▼	▼	▼
Society for the Protection of the Unborn Child <small>26</small>	⊘	⊘	⊘
LIFE <small>27</small>	⊘	⊘	⊘

**Canada**

	<i>In Vitro</i> Fertilization: excess embryos	<i>In Vitro</i> Fertilization: created for research only	Somatic Cell Nuclear Transfer (SCNT) - "Therapeutic Cloning"
<b>SCIENCE</b>			
The Social Sciences and Humanities Research Council of Canada <sup>28</sup>	▼	⊘	⊘
Medical Research Council of Canada <sup>29</sup>	▼	⊘	⊘
Natural Sciences and Engineering Research Council Council of Canada <sup>30</sup>	▼	⊘	⊘
<b>RELIGION &amp; PHILOSOPHY</b>			
Canadian Conference of Catholic Bishops <sup>31</sup>	⊘	⊘	⊘
Canadian Physicians for Life <sup>32</sup>	⊘	⊘	⊘
<b>PUBLIC</b>			
Juvenile Diabetes Research Foundation Canada <sup>33</sup>	▼	⊘	▼
Canadian Cystic Fibrosis Foundation <sup>34</sup>	▼	⊘	⊘
Parkinson Society Canada <sup>35</sup>	▼	⊘	⊘
Heart and Stroke Foundation of Canada <sup>36</sup>	▼	⊘	⊘
Canadian Cancer Society <sup>37</sup>	▼	⊘	⊘
Muscular Dystrophy Association <sup>38</sup>	▼	⊘	▼

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# **A Review of Legislative and Regulatory Activity in the United States, United Kingdom, Canada, and Selected Other Countries**

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This chapter describes the history and recent developments of legislative and regulatory activity of embryonic stem cell (ESC) research in the United States, the United Kingdom, Canada, as well as elsewhere where there has been activity. Most countries are in different stages of development: some have had established guidelines for nearly a decade or more, while others are actively considering legislation and regulations on the subject. This chapter compares their positions from the same viewpoint as the previous chapter, namely the source of ESC cells for research.

The United States declared, in an executive order (President Bush) of August 2001, that public funds may be used on extant ESC lines, but not for the development or use of any newly generated ESC lines. This order did not impede the use of private funds on ESC research, whatever the legal source of cells. Some state legislatures, such as New Jersey — the center of the pharmaceutical industry in the United States — have taken aggressive steps to sanction with controls all forms of ESC research, and encourage investment in this area. Other states, in reaction to pressure from groups concerned about the ethics of ESC research, are looking to endorse and extend the federal ban to the private sector. Current bills before Congress propose varying degrees of increasing regulation.

The United Kingdom has shown the most stewardship of our three countries by confronting this issue head on as early as 1990, with the subsequent establishment of guidelines through the British parliament that regulate but do not ban ESC research.










Canada has recently passed legislation banning all use of deliberately fertilized ova and SCNT (therapeutic cloning) for ESC research, but allows the controlled use of excess embryos from IVF for this purpose.

Australia has recently followed in the steps of the United Kingdom. The European Union is recommending the use of public funds for ESC technology research in nations that permit it, but this has yet to be passed by the European Parliament. China and Singapore currently permit ESC research from all three of the ESC sources, however, Singapore has bills pending in its parliament to limit it. The United Nations has not yet arrived at a consensus on the issue.

There is a wide range of legislative and regulatory activity currently in process in the United States, the United Kingdom, and Canada. The intent of this chapter is to summarize in a tabular format the latest state of play in our own countries, as well as in selected parts of the world. The landscape is constantly changing, however, and this review is only current to early 2004. All tables include the three sources of ESC, and describe the legislation currently in place, and potentially on the horizon.

Key	Current Legislation	Proposed Legislation
✓	In Favor	Allowed with no Restrictions
▼	Controlled	Restrictions
⊘	Opposed	Illegal
□	No legislation in Place	

### Selected Nations and Multinational Organizations

	<i>In Vitro</i> Fertilization: excess embryos		<i>In Vitro</i> Fertilization: created for research only		Somatic Cell Nuclear Transfer (SCNT) - "Therapeutic Cloning"	
	Current Legislation	Proposed Legislation	Current Legislation	Proposed Legislation	Current Legislation	Proposed Legislation
<b>USA Public Funds</b>  1, 2, 3	⊘		⊘		⊘	
<i>Regulatory policy only permits the research of existing ESC lines using public funds, however, private funds may be used towards new and existing ESC lines.</i>						
<b>USA Private Funds</b>  1, 2, 3	□	▼	□	▼	□	▼ ⊘
<b>Canada</b>  4, 5, 6	▼		⊘		⊘	
<b>UK</b>  7	▼		▼		▼	
<b>Australia</b>  8	▼		▼		▼	
<b>EU</b>  9	□	▼	□	▼	□	▼ ⊘
<b>China</b>  10, 11, 12	✓		✓		✓	
<b>Singapore</b>  13	✓	▼	✓	▼	✓	▼
<b>UN</b>  14, 15	□	▼	□	▼	□	▼ ⊘

**United States, by State**

	<i>In Vitro</i> Fertilization: excess embryos		<i>In Vitro</i> Fertilization: created for research only		Somatic Cell Nuclear Transfer (SCNT) - "Therapeutic Cloning"	
	Current Legislation	Proposed Legislation	Current Legislation	Proposed Legislation	Current Legislation	Proposed Legislation
AL <small>16, 17</small>	☐		☐		☐	⊘
AR <small>16, 17</small>	☐		☐		⊘	
CA <small>16, 17</small>	▼		▼		☐	⊘
CT <small>16, 17</small>	☐		☐		☐	⊘
DE <small>16, 17</small>	☐		☐		☐	▼⊘
FL <small>16, 17</small>	☐		☐		☐	⊘
GA <small>16, 17</small>	☐		☐		☐	⊘
IA <small>16, 17</small>	☐		☐		⊘	
IL <small>16, 17</small>	☐	▼	☐	▼	☐	⊘
IN <small>16, 17</small>	☐		☐		☐	⊘
KY <small>16, 17</small>	☐	⊘	☐	⊘	☐	⊘
LA <small>16, 17</small>	☐		☐		☐	⊘
MA <small>16, 17</small>	☐	▼	☐	▼	☐	▼⊘
MD <small>16, 17</small>	☐	▼	☐	▼	☐	▼
MI <small>16, 17</small>	☐	▼⊘	☐	▼⊘	▼	
MO <small>16, 17</small>	☐		☐		☐	▼
ND <small>16, 17</small>	☐		☐		⊘	



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## Some Economic Consequences of Embryonic Stem Cell Policy

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The possible outcomes of ESC research could yield dramatic potential for mankind — from the ability to arrest and reverse the crippling consequence of severe spinal injury, to outright “cures for pervasive diseases like diabetes and Parkinson’s.”<sup>1</sup> That there will be economic consequences associated with the policy decisions that countries reach with respect to stem cell research is indisputable — the quantification of these economic consequences, however, is another matter.

One way to consider the economic consequences of policy decisions regarding ESC research is to examine them in two distinct constructs: the economics of discovery, and the economics of distribution.

### The Economics of Discovery

There are three distinct dimensions to the economics of discovery. The first dimension embraces the conventional financial considerations that are derived from the creation of new and valued knowledge: i.e. the flow of investment capital into research, and the consequential enjoyment of the financial returns generated by those investments. The second dimension is the value derived from the flow of knowledge and human capital. Finally, one must also consider the opportunity costs associated with a decision to forgo discovery.

From the conventional financial perspective, with the creation of new medical knowledge comes the possibility of substantial economic returns that reward the risks taken by first movers, be they nations or private investors, who own the intellectual property developed. All others will be buyers of that intellectual property. The decision today by any nation to limit or forbid stem cell research will relegate that nation to the position of buyer, not creator, and will impose on it the costs associated with that position.

Even if ESC research realizes a small fraction of its promise, the consequences of being a developer are likely to be dramatic. Research and development dollars will flow to those nations that support ESC research activities, and will flow in a boundary-free world along the path of least resistance. The economic dividends resulting from the creation of new knowledge will benefit those that invest in its creation.

Such is the mind set in China, for example, where two years ago, the Ministry of Health announced plans for the construction of a massive stem cell complex in Tianjin. Lu Guangxiu, a Xiangya University medical professor, claimed, “We are not that far behind [the West] anymore.”<sup>2</sup>

The complex will not be completed until 2010. Paul Berg, a Nobel laureate from Stanford observed: “We will either condemn them [the Chinese] as godless members of an evil empire, or we will say ‘Hey, wait a second, we can’t be left out of this race.’”<sup>3</sup>

It is reasonable to conclude that public research funds will not flow to other nations engaged in research that is forbidden at home. There is an interesting variant here in that in the United States, the National Institutes of Health have funded about \$3.5 million through BresaGen in Australia. But the grant came through a U.S. subsidiary.<sup>4</sup> However, that public limitation may lead to an investment opportunity for private capital, thus resulting in the export of private research and development funding elsewhere. This is actually occurring today in the United States through vehicles called limited liability companies and partnerships (LLCs and LLPs), which invest in ESC research in countries like China and Korea. One recent private study indicates that venture financing has raised more than \$625 million from U.S. investors “that seek to commercialize some aspect of stem cell research”<sup>5</sup>. Australia has begun to position itself in global financial markets as a center of biotechnological research, and in the past five years, the number of biotech companies there has doubled to more than 300, with 35 of them publicly listed.<sup>6</sup>

In May 2004 the United Kingdom, seeking an opportunity to participate in the development of knowledge, opened the world’s first stem cell bank to store, characterize and supply stem cells derived from embryonic, fetal, and adult stem cell sources. Here, funding is from public sources — the Medical Research Council and the Biotechnology and Biological Sciences Research Council of the United Kingdom.

It is fascinating to note that some universities in the United States, institutions not usually known for risk taking, have entered the game. Harvard University announced (recently) that it plans to establish a multi-million dollar stem cell institute and will provide free access to 17 new human embryonic stem cell lines.<sup>7</sup> Indeed, this decision by Harvard simply joins it with other institutions that are developing programs independent of federal support.<sup>8</sup>

The second aspect of the economics of discovery — knowledge and human capital — is more amorphous than pure financial returns. In the industrial era, human capital was essentially labor, and it was geographically constrained. Today, human capital is intellectual in nature, and with technology, can be transported without the need of physical relocation.

One of the greatest risks that policies on ESC research may have is in the flight of human capital. In the 1970s and 1980s, Canada saw a flight of scholars and workers in aerospace, finance, software and entertainment to the United States as greater economic returns were to be found south of the border. With the flight of human capital comes not only the loss of the social investment in education of those who “flee,” but also the opportunity for the reinvestment of that education in future generations.

The European Union has recognized the risks of this cost of human capital flight. It has recently created a “scientific visa” in an effort to help ameliorate what “Europe has fretted [about] for the recent decade or more, i.e. ‘brain drain’ to...the U.S.”<sup>9</sup> Whether the “visa” works or not remains to be seen. But the EU’s concern at its loss of intellectual capital is real.

Intellectual capital will flow to its best use. The risk that adheres to any legislation that limits knowledge creation is that those engaged in the creative process will move to a place where they can pursue their research. Coincident with this move is the loss of human capital reserves that have been developed.

The final consideration relates to the cost to society if the investment in and rewards of discovery are borne and enjoyed by countries and investors whose perspectives differs markedly from our own. If a country willingly abdicates its role in stem cell research, one could argue that it also denies itself a seat at the table for later debate on the appropriate or inappropriate uses of the outcomes of the research.

## The Economics of Distribution

Whether the product is alcohol in speakeasies, world-class athletes seeking an advantage through performance enhancing drugs, or Cambodian infants for families seeking to adopt a child, if demand exists, supply channels will be created. If there is demand for the results of ESC research such as cures for crippling diseases, a supply market will arise.

The most significant question is how that market develops and where it exists. Will it be a free market in which the only constraints are those that focus on protecting the consumer from a dangerous product or procedure, such as the current pharmaceutical market? Or, will the conventional marketplace be precluded from participating by legislation banning all such activity?

If any trade whatsoever is precluded and if the product or service is valued, an underground market will arise, as witnessed during Prohibition in the United States. The consequences are predictable: revenues are lost to the government, costs associated with market and consumer abuses are borne by taxpayers, and organized crime and underground markets flourish.

Like prohibition, there is a very significant risk that ESC legislation which precludes a nation's citizens from sharing in the benefits of medical research will force the distribution of that benefit underground. Citizens will lose the protection afforded by the nation's regulatory system, the nation will lose the tax revenues from the provider of the technology, yet it will still bear the costs of any untoward consequences.

Three scholars from the Université de Montréal admonish us with this caveat:

“It is important to avoid passing laws that Canada will regret in ten years. Today's laws may become tomorrow's embarrassments as new technologies appear...Once passed, such laws become impossible to change, even though many patients would like to see research proceed.”<sup>10</sup>

The beneficiaries of the value created from the fruits of ESC research will likely depend on legislative and regulatory policy in each of our countries. The resulting economics of discovery and distribution will ultimately decide the winners and losers in this complex and exciting new field of medical research.

## Chapter Endnotes

- <sup>1</sup> Institute for Stem Cell Research; Press Release April 17, 2003
- <sup>2</sup> *The Wall Street Journal*; March 8, 2002
- <sup>3</sup> Ibid.
- <sup>4</sup> Private study conducted by Capital Run Partners, Seattle. February 19, 2004
- <sup>5</sup> Ibid.
- <sup>6</sup> *Foreign Direct Investment*; April 2, 2003
- <sup>7</sup> *Financial Times*, March 5, 2004, p. 13
- <sup>8</sup> Stanford University, the University of Wisconsin at Madison, the University of Minnesota and the University of California at San Francisco are some of these institutions.
- <sup>9</sup> Ellis Rubenstein quoted in *The Scientist*; December 15, 2003
- <sup>10</sup> Stem Cells in Pluralistic Society: Consequences of Proposed Canadian Legislation; Dorothy C. Wertz, Marie-Hélène Régnier and Bartha Maria Knoppers. Genetics and Society Project, CRDP, Université de Montréal.

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## Conclusions

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1. The way our countries engage in ESC research is likely to have an important influence on our health and well being, and on the economics of discovery and distribution for all our citizens.
2. The debate on how to proceed is fraught with the problems of complex and changing science, an inconsistent framework for discussion, and many stakeholders with varying degrees of influence.
3. The United Kingdom and Canada each have developed their own direction, although somewhat different from each other, while the US is still in the throws of developing a national policy.
4. ESC research is progressing quickly around the world, and arguably ahead of our countries (notably in Asia).
5. The risk-reward equation of choosing to actively engage in ESC research is not generally recognized, nor fully considered.



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